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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group: 3732

Confirmation No.:

Application No.: 10/714,834

Invention: USE OF CYCLIC FORCES TO
EXPEDITE REMODELING OF
CRANIOFACIAL BONES

Applicant: Jeremy Jian Mao

Filed: November 14, 2003


Attorney

Docket: 21726/99563

Examiner: Bumgarner, Melba N.

I hereby certify that this correspondence is being
deposited with the United States Postal Service as
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1450, Alexandria, VA 22313-1450

on September 27, 2005


Alice O. Martin
Registration No. 35,601

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Adriana Da Silveira, have read the patent application "Use of Cyclic Forces to Expedite Remodeling of Craniofacial Bones" (10/714,834). A copy of my curriculum vitae is appended to indicate my expertise in the area of the invention described therein. I am an orthodontist specialized in treating children and adults with craniofacial problems and malformations and have a PhD degree in Craniofacial Biology.

I declare that I have no relationship to the patent application captioned above and will not benefit financially from its commercial development.

Exhibit A

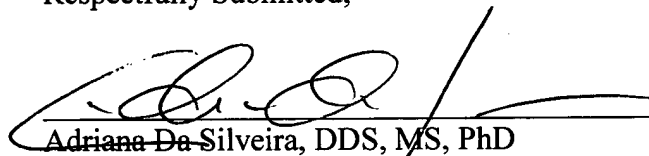
I declare that:

1. I understand that the examiner is of the opinion that a person working in the area of craniofacial rehabilitation could not apply the cyclic forces described in the patent application to cranial sutures to induce osteogenesis without a device to deliver cyclic forces described in the application.
2. In my opinion, the patent application provides sufficient information to those practicing in this area to apply cyclic forces to induce osteogenesis in cranial sutures.
3. Moreover, I believe this device would be extremely beneficial to patients with syndromes that have growth problems of craniofacial bones. This device has the potential to induce osteogenesis with its clinical application, potentially minimizing the need for surgery and lengthy treatments.
4. These results have been demonstrated in animal research.
5. This would be extremely helpful in clinical practice, especially when applied to known devices such as Headgears and face masks.
6. I am excited with the potential results and looking forward to be able to use this device in my own clinic.

• • •

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,


Adriana Da Silveira, DDS, MS, PhD
Assistant Professor
Chief of Orthodontics
The Craniofacial Center and Department of
Orthodontics

Date: 9/26/05

Curriculum Vitae

Adriana Costa Da Silveira, DDS, MS, PhD

University of Illinois at Chicago

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Education:

- Doctor of Dental Science (D.D.S.), University of Illinois at Chicago, 2002-2004.
- Certificate in Orthodontics, Eastman Dental Center/ University of Rochester, 1998-2000.
- Ph.D. in Oral Biology, University of Florida, 1993-1998.
- Master of Science in Oral Biology, University of Florida, 1993-1996.
- Doctor of Dental Science (D.D.S.), Universidade do Estado do Rio de Janeiro, Rio de Janeiro, Brazil, 1986-1990.

Academic Appointments:

- Medical Staff Appointment, University of Illinois at Chicago Hospital, June 2003.
- Clinical Assistant Professor at the University of Illinois at Chicago, Department of Orthodontics, College of Dentistry, September 2000.
- Clinical Assistant Professor at the University of Illinois at Chicago, Department of Surgery, College of Medicine, October 2000.
- Chief of Orthodontics at The Craniofacial Center at the University of Illinois at Chicago, September 2000.
- Director of Research at the Craniofacial Center at the University of Illinois at Chicago, September 2000.

Licenses and Board Certifications:

- American Board of Orthodontics, board certified, July 2005.
- National Dental Board Examination, Part II, August 2005.
- CRDTS Regional Dental Boards examination, May 2005.
- National Dental Board Examination, Part I, August 2001.
- American Board of Orthodontics, Part II examination, May 2001.
- Restricted Dental Faculty License, State of Illinois, September 2000.

Teaching Activities:

- Coordinator and lecturer of Craniofacial Anomalies courses (ORTD524 and ORTD 525), Department of Orthodontics, UIC, 2000- present.
- Lectures in growth of craniofacial structures, craniofacial anomalies, orthognathic surgery and laboratory seminars in the Preclinical Orthodontic Course (ORTD 323, 338 and 348), College of Dentistry, UIC, 2001-present.
- Lecture of review of Orthodontics for the National Board Exam for senior dental students, College of Dentistry, UIC, 2001- 2002.
- Lecture in Cleft Lip and Palate for Maxillofacial Prosthetics Seminar (PROS 621), College of Dentistry, UIC, 2002 - 2004.
- Lecture in Craniofacial Clinical Research for Seminar in Oral Sciences I (OSCI 580-I), College of Dentistry, UIC, 2003 - 2005.
- Committee member, graduate advisor and/or research supervisor of numerous Master of Sciences students, Master in Bioengineering students, Orthodontic residents, Craniofacial Orthodontic fellows, Plastic Surgery residents, medical and dental students, 2001- present.
- Course Director of Predoctoral Preclinical and Clinical Orthodontic Courses (ORTD 323, 338 and 348), College of Dentistry, University of Illinois at Chicago, October 2000 – December 2002.

Awards:

- Orthodontic Faculty Development Fellowship Award from the American Association of Orthodontists Foundation, July 2004.
- Invited to the Hatton Award Competition from the American Association of Dental Research (AADR), Minneapolis Meeting, March 1998.
- Colgate-Palmolive/ Hispanic Dental Association Foundation Scholarship/Grant received after submitting a research proposal in the form of competition, September 1997.
- Florida Brazil Institute Tuition Exemption Award, May 1997 and September 1997.
- Second Place in the Biological Sciences Group in the Graduate Student Forum Competition in the University of Florida, April 1996.
- Grinter Award from the Graduate School of the University of Florida received as a first year graduate student, October 1993.

Grants:

Funded:

- Wach Fund from the College of Dentistry, University of Illinois at Chicago, "Expression of matrix metalloproteinases during fusion of rat cranial sutures", October 2000.

Work Experience:

- Research laboratory technical in the Department of Biochemistry and Molecular Biology of the University of Florida, August 1992 - 1993.

- General Dentist in private practice in Fortaleza, Brazil, October 1990 - November 1991.

Professional Association Memberships:

- American Association of Orthodontists (AAO), American Dental Association (ADA), International Association of Dental Research (IADR), American Cleft-Palate-Craniofacial Association (ACPA), Chicago Dental Society (CDS).
- Reviewer of the Angle Orthodontist (2004- present).
- Reviewer of the American Journal of Orthodontics and Dentofacial Orthopedics (2001).
- Reviewer of the Cleft Palate-Craniofacial Journal (2002- present)
- Reviewer of the Frontiers in Bioscience Journal, special issue: Biomimetics and Engineering of Skeletal Tissues (2002).
- Program Committee member of the American Cleft-Palate-Craniofacial Association (ACPA) Meeting for 2006, Vancouver, BC.
- Organizing Committee member of the 11th International Symposium on Dentofacial Development and Function, June 2006, Chicago, IL.
- Continue Education Committee member of the American Cleft-Palate-Craniofacial Association (ACPA), (2001- present).

Skills:

- Languages: Portuguese, English and Spanish.

Presentations:

- **Da Silveira A**, Daw J. Orthodontic and Surgical management of Craniofacial Malformations. Chicago Academy of Dental Research, **invited speaker**, Chicago, April 2005.
- **Da Silveira A**. Craniofacial Imaging for the 21st Century: the quest for 3 Dimensional Methodologies. Illinois Orthodontic Alumni Association Year 2004 Quadrennial Meeting, **invited speaker**, Chicago, September 2004.
- **Da Silveira A**. Comparative Nasal Effects of Two Different Kinds of Palatal Expanders. Tenth International Symposium on Dentofacial Development and Function, Bahia, Brazil, August 2004.
- **Da Silveira A**, Martinez O, Da Silveira D, Daw J, Cohen M. Comparison of 3D facial images generated with a laser surface scanner to corresponding facial casts from cleft infants. American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- **Da Silveira A**, Oliveira N, Gonzalez S, Shahani M, Reisberg D, Daw J and Cohen M. Modified nasal alveolar molding appliance for management of cleft lip defect, American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- **Da Silveira A**. Imaging Facial Deformities: Learning the Treating Orthodontist's Perspective, **invited speaker**, American Dental Education Association Annual Meeting, Seattle, March 2004.
- **Da Silveira A**. Craniofacial Imaging Research for the 21st Century: the Quest for 3 Dimensional Methodologies. Lunch and Learning session, **invited speaker**, International Association of Dental Research Meeting, Goteborg, Sweden, June 2003.

- **Da Silveira A**, Daw J. Facial Esthetics for the 21st Century: Dental, Skeletal and Soft Tissue Considerations, **invited speaker**. American Association of Orthodontists Meeting, Honolulu, May 2003.
- Kusnoto B, Pan Y, Kanetaka H, Evans C, **Da Silveira A**. Assuring Secure Digital Images for Medical / Dental Records. Seeing is Believing? American Association of Orthodontists Meeting, Honolulu, May 2003.
- **Da Silveira A**, Cohen M. The Use of 3D Surface Laser Scanner for Documentation of Cleft Lip and Palate Infants, American Cleft Palate Association Meeting, Seattle, May 2002.
- **Da Silveira A**, Oliveira N, Gonzalez S, Kusnoto B. Three Dimensional Assessment of Growth Changes on Dental Casts of Non-Syndromic Bilateral Complete Cleft Lip and Palate Patients. American Cleft Palate Association Meeting, Seattle, May 2002.
- **Invited Keynote Speaker** at the International Update on Craniofacial Clefts and the First National Meeting of Indian Society of Cleft Lip, Palate and Craniofacial Anomalies, Mumbai, India, March 2002.
- **Da Silveira A**. "Three-dimensional assessment of morphological changes of the maxillary arch: A comparison of two kinds of palatal expanders." **Invited speaker**, Twenty-eighth Annual Conference on Craniofacial Research, Moyer's Presymposium, University of Michigan, Ann Arbor, February 2002.
- **Da Silveira A**, Du Y and Brinkley L. Occurrence of MMPs, TIMPs, and their mRNAs during murine facial morphogenesis International Association of Dental Research Annual Meeting, San Francisco, 1996.
- **Da Silveira A**, Du Y and Brinkley L. Appearance of metalloproteinases and serine proteases during murine facial development. American Association of Dental Research Annual Meeting, San Antonio, 1995.

By the students:

- Oliveira, N*. Assesment of Rapid Maxillary Expansion and Its Effects on the Nasal Cavity. Ortho Resident/ Student Scholar Program Competition, AAO Annual Meeting, San Francisco, May 2005.
- Daw J, **Da Silveira A**, Clark, A*. Congenital absence of the Sternocleidomastoid muscle with ipsilateral hemifacial microsomia: a case report. Oral Presentation, American Cleft Palate-Craniofacial Association Meeting, Myrtle Beach, April 2005.
- Morris D*, **Da Silveira A**, Martinez O, Da Silveira D, Patel P, Daw J, Cohen M. Describing facial clefts: reconciling the difference between laser scanning and facial molding. Oral Presentation, American Cleft Palate-Craniofacial Association Meeting, Myrtle Beach, April 2005.
- Oliveira N*, **Da Silveira A**, Viana G. Long-term evaluation of airway patency after Rapid Maxillary Expansion. Poster Presentation, 83rd General Session & Exhibition of the IADR, Baltimore, March 2005.
- Oliveira N*, **Da Silveira A**, Kusnoto B, Smith B, Evans C. Objective assessment of the nasal cavity and the maxillary arch after Rapid Palatal Expansion. Poster Presentation, Clinic and Research Day, UIC, February 2005.
- Oliveira N*, **Da Silveira A**, Viana G. Effects of Rapid Maxillary Expansion and on the nasal cavity's cross-sectional area, volume and airway resistance. Oral Presentation, GLAO&MSO Combined Annual Session, Chicago, 2004.

- Bock D*, **Da Silveira A**, Daw J, Ziai M. Parry-Romberg syndrome: case report of an early onset. American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- Gonzalez S*, **Da Silveira A**, Viana G. Cultural perspectives, beliefs and myths associated with the birth of a cleft lip and palate child. American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- Gonzalez S*, **Da Silveira A**, Daw J, Cohen M. Prevalence of intranasal teeth in cleft lip and palate. Poster presentation at the American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- Oliveira N*, **Da Silveira AC**, Viana G. Comparison of nasal cavity effects of Haas versus Hyrax expanders, Poster Presentation, 82nd General Session & Exhibition of the International Association of Dental Research, Honolulu, March 2004.
- Bock D*, **Da Silveira A**, Daw J, Ziai M. Parry-Romberg syndrome: case report of an early onset. UIC College of Dentistry Clinic and Research Day, February 2004.
- Ziai M*, Bock D, **Da Silveira A**, Daw J. Natal teeth: a potential impediment to nasoalveolar molding in the cleft lip and palate infant. UIC College of Dentistry Clinic and Research Day, February 2004.
- Gonzalez S*, Cohen M, Daw J, **Da Silveira A**. Presurgical Orthopedics for Cleft Lip and Palate, XI Congreso Latinoamericano de Odontología Pediátrica, Cartagena, Colombia, June 2002.
- Oliveira N*, Sadowsky C, Kusnoto B, **Da Silveira A**. Three-Dimensional Morphological Assessment of the Maxillary Arch After Palatal Expansion, Sigma Xi Scientific Research Society Award, The University of Illinois at Chicago Chapter, Chicago, April 2002.
- Oliveira N*, Sadowsky C, Kusnoto B, **Da Silveira A**. Three-Dimensional Morphological Assessment of the Maxillary Arch After Palatal Expansion. International Association of Dental Research Meeting, San Diego, March 2002.
- Oliveira N*, Sadowsky C, Kusnoto B, **Da Silveira A**. Three-Dimensional Morphological Assessment of the Maxillary Arch After Palatal Expansion, UIC Clinic and Research day, February, 2002.

Publications:

- Al-Mubarak R, **Da Silveira A**, Mao JJ (2005). Expression and mechanical modulation of matrix metalloproteinase-1 and -2 genes in facial and cranial sutures. Cell Tissue Res. 2005 Sep;321(3):465-71. Epub 2005 Jul 27
- Shahani M, **Da Silveira A**, Ziai M, Uribe A. Team Management of An Unusual Case of Williams' Syndrome with Cleft Palate and Severe Feeding Problems. Submitted to the Cleft Palate – Craniofacial Journal.
- Ziai M, Bock D, **Da Silveira A**, Daw J (2005). Natal Teeth: A Potential Impediment to Nasoalveolar Molding in Cleft Lip and Palate Infants. J Craniofac Surg 16(2): 262-266.
- Collins J, Ramamoorthy K, **Da Silveira A**, Patston P, Mao J (2005). Expression of Matrix Metalloproteinase genes in the rat intramembranous bone during postnatal growth and upon mechanical stresses. J Biomech 38(3):485-92.
- Oliveira N, **Da Silveira A**, Kusnoto B, Viana G (2004). Three-dimensional Assessment of Morphological Changes of the Maxilla: a Comparison of Two Kinds of Palatal Expanders. Am J Orthod Dentofacial Orthop 126(3):354-62.

- **Da Silveira A**, Martinez O, Da Silveira D, Daw J, Cohen M (2004). Three-Dimensional Technology for Documentation and Record Keeping for Patients with Facial Clefts. *Clin Plast Surg*. Apr;31(2):141-8.
- **Da Silveira A**, Daw J, Kusnoto B, Cohen M, Evans C (2003). Craniofacial applications of three-dimensional laser surface scanning. *J Craniofac Surg* 14(4): 449-456.
- **Da Silveira A**, Oliveira N, Gonzalez S, Shahani M, Reisberg D, Daw J, Cohen M. (2003) Modified Nasoalveolar Molding Appliance for Management of Cleft Lip Defect. *J Craniofac Surg* 14(5):700-3.
- Yamachika S, Nanni JM, Nguyen KH, Garces L, Lowry JM, Robinson CP, Brayer J, Oxford GE, **da Silveira A**, Kerr M, Peck AB, Humphreys-Beher MG (1998). Excessive synthesis of matrix metalloproteinases in the exocrine tissues of the NOD mouse models for Sjögren's syndrome. *Journal of Rheumatology* 25: 2371-80.
- Broverman R., Nguyen K., **da Silveira A.**, Brinkley L., Macauley S., Zeng T., Tarnuzzer R., Schultz G., Humphreys-Beher M. (1998). Changes in the Expression of Extracellular Matrix (ECM) and Matrix Metalloproteinases (MMP) of Proliferating Rat Parotid Acinar Cells. *J Dental Res* 77: 1504-14.

Abstracts:

- Daw J, **Da Silveira A**, Clark, A. Congenital absence of the Sternocleidomastoid muscle with ipsilateral hemifacial microsomia: a case report. American Cleft Palate-Craniofacial Association Meeting, Myrtle Beach, April 2005.
- Morris D, **Da Silveira A**, Martinez O, Da Silveira D, Patel P, Daw J, Cohen M. Describing facial clefts: reconciling the difference between laser scanning and facial molding. American Cleft Palate-Craniofacial Association Meeting, Myrtle Beach, April 2005.
- Smith B, **Da Silveira A**, Ziai M, Dolter C, Shahani M. Profiles of CPO and CLP patients: One team's experience. American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- **Da Silveira A**, Oliveira N, Gonzalez S, Shahani M, Reisberg D, Daw J and Cohen M. Modified nasal alveolar molding appliance for management of cleft lip defect, American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- Bock D, **Da Silveira A**, Daw J, Ziai M. Parry-Romberg syndrome: case report of an early onset. American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- Gonzalez S, **Da Silveira A**, Viana G. Cultural perspectives, beliefs and myths associated with the birth of a cleft lip and palate child. American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- **Da Silveira A**, Martinez O, Da Silveira D, Daw J, Cohen M. Comparison of 3D facial images generated with a laser surface scanner to corresponding facial casts from cleft infants. American Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- Gonzalez S, **Da Silveira A**, Daw J, Cohen M. Prevalence of intranasal teeth in cleft lip and palate. Cleft Palate Association 61st Annual Meeting, Chicago, March 2004.
- Oliveira N, **Da Silveira AC**, Viana G. Comparison of nasal cavity effects of Haas versus Hyrax expanders, 82nd General Session & Exhibition of the IADR, Honolulu, March 2004.
- **Da Silveira A**, Cohen M. The Use of 3D Surface Laser Scanner for Documentation of Cleft Lip and Palate Infants, American Cleft Palate Association Meeting, Seattle, 2002.

- Oliveira N, Gonzalez S, Kusnoto B, **Da Silveira A**. Three Dimensional Assessment of Growth Changes on Dental Casts of Non-Syndromic Bilateral Complete Cleft Lip and Palate Patients. American Cleft Palate Association Meeting, Seattle, 2002.
 - Oliveira N, Sadowsky C, Kusnoto B, **Da Silveira A**. Three-Dimensional Morphological Assessment of the Maxillary Arch After Palatal Expansion. International Association of Dental Research Meeting, San Diego, 2002.
 - **Da Silveira A**, Du Y and Brinkley L. Occurrence of MMPs, TIMPs, and their mRNAs during murine facial morphogenesis J Dental Res 75 (IADR Absts): 225, 1996.
 - **Da Silveira A**, Du Y and Brinkley L. Appearance of metalloproteinases and serine proteases during murine facial development. Journal of Dental Research 74 (IADR Absts): 65, 1995.
 - Denslow ND, Nguyen HP, **Da Silveira AC**, Parten B and Ryan JW. Partial Sequence of Guinea Pig Aminopeptidase P: A Member of the Proline Peptidase Family. Abstract for the Seventh Symposium of the Protein Society, 1993.
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